1899A BILLINGSGATE CIRCLE /RICHMOND, VIRGINIA 23233-4243 / 804 / 740-9376 / FAX 804 / 740-940 7

99 NOV 23 P3:13

November 18, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Docket No. 99N-2874

REGULATORY RESOURCES

Dear Madam/Sir:

This letter is to provide comments on the Development of Guidance Documents for Medical Devices Regulated by CBER (64 FR 180, page 505 17). I attended the teleconference on November 15, 1999 and agree with many of the industry speakers' suggestions for improvement, including earlier industry involvement in guidance development, better coordination between CDRH and CBER for the devices they share, and more efficiency in the review of premarket submissions for device manufacturers and licensed device users. I also agree with the speakers who advocated CBER's use of international, harmonized standards for devices in lieu of specific guidance, and hope that international harmonization of standards for blood and plasma products will be a high priority at FDA in the future.

The following additional suggestions, which were not included in the earlier comments, are offered for consideration by CBER staff as work proceeds on the device guidance plans:

1. Current and future CBER guidance documents need to have special reviews to detect and eliminate arbitrary limits and standards. Such limits, though well-intentioned, often become elevated to "standard of practice" by FDA investigators and plaintiffs' attorneys, despite FDA's own disclaimers against enforceability. Standards that are accepted as "current practice" today can quickly become inappropriate or impossible to meet with the pace of change underway in blood and plasma operations. If a limit or standard is essential to public. health, then it should be incorporated into regulation.

99N-2874

C2

2. Where feasible, guidance should be developed and issued separately for CBER device ***manufacturers*** and device ***users*** (the latter, often US licensed facilities). Clearly identifying the intended audience will avoid confusion over obligations and responsibilities, and prevent difficult situations in which FDA guidance places manufacturers in the position of imposing non-statutory requirements on their customers, or vice versa.

CBER's willingness to improve device regulatory processes and practices has been encouraging. There is much that still needs to be done. Continued public meetings and a culture of listening will maximize the potential for successful implementation of FDAMA, and compliance with statutory requirements.

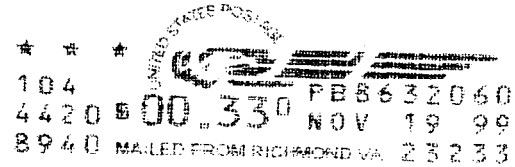
Sincerely,

Emily B. Rossiter

Emily B. Rossiter
President

1899A BILLINGSGATE CIRCLE/ RICHMOND, VIRGINIA 23233-4243

REGULATORY
RESOURCES



Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

20857X0061